

Technical Information

September 2004

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Cremophor® EL

® = Registered trademark of
BASF Aktiengesellschaft

Solubiliser and emulsifying agent for the human and veterinary pharmaceutical industries; used in aqueous preparations of hydrophobic substances, e. g. fat-soluble vitamins and essential oils.

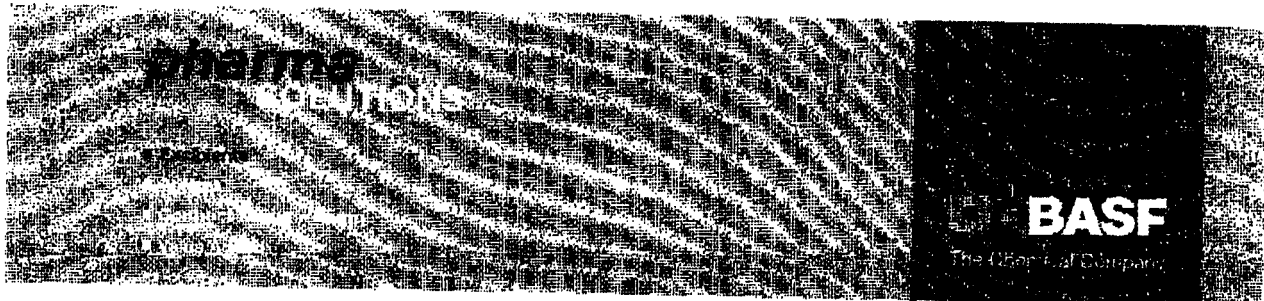


EXHIBIT B

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Cremophor® EL

Pharmacopoeias

Ph.Eur. 4th edition, 2002: Castor oil, polyoxyl and USP27-NF22: Polyoxyl 35 Castor Oil

Chemical nature

Cremophor® EL is a nonionic solubiliser and emulsifier made by reacting castor oil with ethylene oxide in a molar ratio of 1 : 35. ←

Composition

The main component of Cremophor® EL is glycerol polyethylene glycol ricinoleate. Together with fatty acid esters of polyethylene glycol, this forms the hydrophobic part of the product. The smaller hydrophilic part consists of free polyethylene glycols and ethoxylated glycerol.

Description

Cremophor® EL is a pale yellow oily liquid that is clear at temperatures above 26°C. It has a faint but characteristic odour. ←

The hydrophilic-lipophilic balance (HLB) lies between 12 and 14.

The critical micelle concentration (CMC) lies at approx. 0.02%.

Solubility

Cremophor® EL forms clear solutions in water. It is also soluble in many organic solvents, e.g. ethyl alcohol, n-propyl alcohol, isopropyl alcohol, ethyl acetate, chloroform, carbon tetrachloride, trichloroethylene, toluene and xylene. ←

In contrast to anionic emulsifying agents, Cremophor® EL becomes less soluble in water at higher temperatures. Thus, aqueous solutions become turbid at a certain temperature.

Cremophor® EL is miscible with all the other Cremophor® grades and, on heating, also with fatty acids, fatty alcohols and certain animal and vegetable oils. It is thus miscible with oleic and stearic acids, dodecyl and octa-decyl alcohols, castor oil, and a number of lipid-soluble substances.

Specification

